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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,393	02/20/2002	Larry E. Morrison	01886-071001/ V0079	1580

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EXAMINER

SAKELARIS, SALLY A

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/081,393

Applicant(s)

MORRISON ET AL.

Examiner

Sally A. Sakelaris

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 8-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/05 11/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This action is written in response to applicant's correspondence submitted 2/2/2005.

Claim 1 has been amended, claims 8-20 have been withdrawn, and claim 21 has been added.

Claims 1-21 are pending, claims 1-7 and 21 are examined herein. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow.

Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

#### *THE FOLLOWING IS A NEW REJECTION NECESSITATED BY APPLICANT'S*

#### *AMENDMENT TO THE CLAIMS*

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 21 is indefinite over the recitation of "selected from the group consisting essentially of" as it is unclear what elements of the group are omitted. As the claim includes a grouping, but its constituents are only essentially present, it is not clear what the members of the group are meant to encompass. Appropriate correction is suggested to correct this presently recited improper Markush group that makes that claim indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinkel et al.(US Patent 5,856,097: January 5, 1999).

This rejection is based on the fact that “comprising” language of the claims and “consisting essentially of” language newly added remains open language and allows for any other step(s) or material to be added in the claimed invention.

With regard to claim 1, Pinkel et al. teach a set of chromosomal probes comprising a 5p chromosome arm probe and a 20q chromosome arm probe(Table 4 column 48).

With regard to claims 2-5, Pinkel et al. teach the set of chromosomal probes, wherein different detection moieties are coupled to the two probes comprising fluorescent labels(Column 51, line 8 to column 52, line 42 and Figures 2, 5, and 6).

With regard to claim 6, Pinkel et al. inherently teach a set of chromosomal probes comprising the three probes: a 5p probe, a 8q24 locus specific probe and 7p probe and 17q21 locus specific probe (Column 48, table 4 and figure 17).

With regard to claim 7, Pinkel et al. inherently teach the set of chromosomal probes comprising a 5p probe, a 8q24 locus specific probe and 20q chromosome arm probe and 7p locus specific probe (Column 48, Table 4 and Figure 17).

It should be noted that the inherency argument is based on the fact that Pinkel et al. teach broadly all chromosomal probes (Figure 17) as Pinkel et al. states, “When CGH is applied, for example, in the fields of tumor cytogenetics and prenatal diagnosis, it provides methods to determine whether there are abnormal copy numbers of nucleic acid sequences *anywhere* in the genome of a subject tumor cell or fetal cell or the genomes from representative cells from a tumor cell population or from a number of fetal cells, without having to prepare condensed chromosome spreads from those cells”(Column 3, lines 32-39). Although the specific numbers such as 5p15 and 7p12 are not mentioned by Pinkel et al., these probes are inherently present in the combination probes of Pinkel et al. since “it provides methods to determine whether there are abnormal copy numbers of nucleic acid sequences *anywhere* in the genome of a subject tumor cell”.

Moreover, MPEP 2123 also states that “a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 10 USPQ 2d 1843 (Fed. Cir. 1989).” Although the Pinkel et al. reference uses certain combinations of probes to detect certain loci on the chromosome, Pinkel et al. teach that such probes can detect abnormal copy numbers of nucleic acid sequences *anywhere* in the genome of a subject tumor cell. Moreover, MPEP 2111 states, “Claims must be given their broadest reasonable interpretation”. “During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification”. Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than it is justified. In re Prater, 415 F.2d 1393, 1404-05,

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162 USPQ 541, 550-51 (CCPA 1969)". In this case, in presence the of "comprising" language of the claims, any combination of probes as taught by Pinkel et al., can be used for detecting abnormal copy numbers of nucleic acid sequences anywhere in the genome of a subject tumor cell.

### ***Response to Arguments***

Applicant's arguments filed 6/1/2004 have been fully considered but they are not persuasive. Applicant first argues on page 9 of their response that "Claim 1 has been amended to delete the recitation of probe sets explicitly taught by Pinkel et al." and furthermore states that "claim 21 was added to the claim set to include these deleted probe sets using partially closed language". Applicant traverses the rejection on the grounds that "the classes of constituents of Pinkel et al. are not sufficiently limited or well delineated to enable one of skill in the art to arrive at Applicant's claimed probe set"(pg. 10) and further that "the mere fact that applicant's claimed probe sets hybridize to amplified loci in the genome of a subject tumor cell does not render Applicant's claimed invention unpatentable over Pinkel et al. merely because Pinkel et al. provides methods for determining abnormal copy numbers of nucleic acid sequences". Lastly, applicant argues that "one skilled in the art would not be able to practice Applicant's claimed invention based on the teachings of Pinkel et al. While applicants' amendments and arguments are noted, they are not found to be convincing. First, since the claims use open language, they are limited to only these specific loci probes. Instead they are limited to anything comprising minimally of these probes. Even arguendo, if closed language is used, the claims would still be anticipated by Pinkel et al. as any probe in the genome is inherent in their methods. Lastly, it is maintained that one of skill in the art would be able to practice Applicant's claimed invention

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based upon the teachings of Pinkel et al. since Pinkel et al. teaches probe hybridization to every location of the genome.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

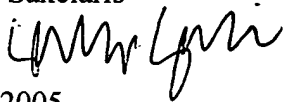
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sally Sakelaris



4/22/2005



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